DOCUMENT-IDENTIFIER: US 6262107 B1
TITLE: Water soluble paclitaxel prodrugs

Abstract Text (1):
Disclosed are water soluble compositions of paclitaxel and docetaxel formed by conjugating the paclitaxel or docetaxel to a water soluble chelator, polyethylene glycol or polymer such as poly (1-glutamic acid) or poly (1-aspartic acid). Also disclosed are methods of using the compositions for treatment of tumors, auto-immune disorders such as rheumatoid arthritis and for prediction of paclitaxel uptake by tumors and radiolabeled DTPA-paclitaxel tumor imaging. Other embodiments include the coating of implantable stents for prevention of restenosis.

Brief Summary Text (25):
The finding that paclitaxel also inhibits restenosis after balloon angioplasty indicates that the water soluble paclitaxels and docetaxels of the present invention will find a variety of applications beyond direct parenteral administration (WO 9625176). For example, it is contemplated that water soluble paclitaxel will be useful as a coating for implanted medical devices, such as tubings, shunts, catheters, artificial implants, pins, electrical implants such as pacemakers, and especially for arterial or venous stents, including balloon-expandable stents. In these embodiments it is contemplated that water soluble paclitaxel may be bound to an implantable medical device, or alternatively, the water soluble paclitaxel may be passively adsorbed to the surface of the implantable device. For example, stents may be coated with polymer-drug conjugates by dipping the stent in polymer-drug solution or spraying the stent with such a solution. Suitable materials for the implantable device should be biocompatible and nontoxic and may be chosen from the metals such as nickel-titanium alloys, steel, or biocompatible polymers, hydrogels, polyurethanes, polyethylenes, ethylenevinyl acetate copolymers, etc. In a preferred embodiment the water soluble paclitaxel, especially a PG-paclitaxel conjugate, is coated onto a stent for insertion into an artery or vein following balloon angioplasty. The invention may be described therefore, in certain broad aspects as a method of inhibiting arterial restenosis or arterial occlusion following vascular trauma comprising administering to a subject in need thereof, a composition comprising paclitaxel or docetaxel conjugated to poly-1-glutamic acid or poly-1-aspartic acid. In the practice of the method, the subject may be a coronary bypass, vascular surgery, organ transplant or coronary or arterial angioplasty patient, for example, and the composition may be administered directly, intravenously, or even coated on a stent and the stent is implanted at the sight of vascular trauma.

Brief Summary Text (26):
An embodiment of the invention is, therefore, an implantable medical device, wherein the device is coated with a composition comprising paclitaxel or docetaxel conjugated to polyglutamic acids or polyaspartic acids in an amount effective to inhibit smooth muscle cell proliferation. A preferred device is a stent coated with the compositions of the present invention as described herein, and in certain preferred embodiments, the stent is adapted to be used after balloon angioplasty and the coating is effective to inhibit restenosis.

Detailed Description Text (8):
In certain embodiments of the invention, a stent coated with the polymer-paclitaxel conjugates may be used to prevent restenosis, the closure of arteries following balloon angioplasty. Recent results in clinical trials using balloon-expandable stents in coronary angioplasty have shown a significant benefit in patency and the reduction of restenosis compared to standard balloon angioplasty (Serruys et al., 1994). According to the response-to-injury hypothesis, neointima formation is associated with increased cell proliferation. Currently, popular opinion holds that the critical process leading to vascular lesions in both spontaneous and accelerated

atherosclerosis is smooth muscle cell (SMC) proliferation (Phillips-Hughes and Kandarpa, 1996). Since SMC phenotypic proliferation after arterial injury mimics that of neoplastic cells, it is possible that anti-cancer drugs may be useful to prevent neointimal SMC accumulation. Stents coated with polymer-linked anti-proliferative agents that are capable of releasing these agents over a prolonged period of time with sufficient concentration will thus prevent ingrowth of hyperplastic intima and media into the lumen thereby reducing restenosis.

Detailed Description Text (92):
Serruys et al., "A comparison of balloon-expandable-stent implantation with balloon angioplasty in patients with coronary artery disease," N. Engl. J. Med., 331:489-495, 1994.

DOCUMENT-IDENTIFIER: US 6265016 B1
TITLE: Process for the preparation of slippery, tenaciously adhering, hydrophilic polyurethane hydrogel coatings, coated polymer and metal substrate materials, and coated medical devices

Abstract Text (1):
A process for the preparation of slippery, hydrophilic polyurethane hydrogel coating compositions, and materials composed of a polymeric plastic or rubber substrate or a metal substrate with a coating of a slippery, hydrophilic polyurethane hydrogel thereon, such that the coating composition tenaciously adheres to the substrate, are disclosed. The coating compositions and coated materials are non-toxic and biocompatible, and are ideally suited for use on medical devices, particularly, catheters, catheter balloons and stents. The coating compositions, coated materials and coated devices demonstrate low coefficients of friction in contact with body fluids, especially blood, as well as a high degree of wear permanence over prolonged use of the device. The hydrogel coating compositions are capable of being dried to facilitate storage of the devices to which they have been applied, and can be instantly reactivated for later use by exposure to water.

Brief Summary Text (6):
Stent catheters for use in vascular disease benefit from the characteristics imparted by a good slippery coating. Stent catheter delivery systems used in gastroenterology for opening of biliary passageways also benefit from a slippery coating with regard to traversing passageways leading to the site.

Brief Summary Text (23):
The present invention encompasses cohesive, biocompatible, high water content, slippery polyurethane hydrogel coatings which are covalently bonded to and tenaciously adhere to plasma-treated polymeric plastic or rubber substrates, or chemically-treated metallic substrates, such as are utilizable for medical devices, which satisfy all of the above requirements. The present invention encompasses the tenaciously adhering coating compositions themselves, as well as materials composed of polymeric plastic, rubber or metal substrates coated with the coating compositions, and products fabricated from the coated materials, including, especially, coated medical devices such as catheters, catheter balloons and stents. The present invention also encompasses methods for applying such protective, wear-resistant, tenaciously adhering and biocompatible slippery barrier coatings to polymeric plastic or rubber substrates, and to metal substrates, particularly, to substrates for use in medical devices. The cohesively bonded, tenaciously adhering, slippery coating compositions and materials of the present invention are biocompatible, highly suited for use in contact with blood, demonstrate a low coefficient of friction with body fluids and a high degree of permanence when applied to a wide variety of medical devices in contact with various body fluids.

Detailed Description Text (28):
Range finding tests with respect to concentration effects of the PU hydrogel intermediates (Example 2 and others) showed that suitable hydrogel coatings on the substrate surface are possible when the solids content of the coatings solution is within the range of from about 1.5% to about 6%, and when the dip time is from about 10 seconds to about 30 seconds. However, it is within the realm and scope of the invention to stay at the lower concentration range or even below, if the dipping time is extended, or relatively more aggressive solvents are used during the initial dipping procedure. Various known contacting methods, including spray coating, are also feasible. The insertion time of the device into the coating solution has a pronounced effect upon the quality of the coating. Other measures which influenced the coatings thickness and quality were the use of somewhat higher boiling solvents such as cellosolve acetate (UCC) and other similar slower evaporating materials as co-solvents with the lower boiling products such as MEK, ethers, and the like. Other

materials which proved useful for the achievement of uniform coatings included minute quantities of surface active agents, for example, TERGITOL.RTM.X-100 (UCC) and thixotropic agents, such as amorphous silicas and other materials which are known to influence the quality and application of coatings to various substrates.

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DOCUMENT-IDENTIFIER: US 6306176 B1
TITLE: Bonding layers for medical device surface coatings

Abstract Text (1):
The medical device is coated with a thin coherent bond coat of acrylics, epoxies, acetals, ethylene copolymers, vinyl polymers containing hydroxyl, amine, carboxyl, amide or other reactive groups, and copolymers thereof. Outer layers may be applied and remain adherent to the substrate in water for an extended period. The bond coat may comprise cross linkers such as urea resins, melamines, isocyanates, and phenolics. Preferred polymers include vinylpyrrolidone-vinyl acetate, styrene acrylic polymer, ethylene acrylic acid copolymer, carboxyl function acrylic polymer, hydroxyl function acrylic polymer, and acrylic dispersion polymer. The coatings may be applied to inert metal or plastic surfaces of medical devices such as needles, guide wires, catheters, surgical instruments, equipment for endoscopy, wires, stents, angioplasty balloons, wound drains, arteriovenous shunts, gastroenteric tubes, urethral inserts, laparoscopic equipment, pellets, and implants. Methods of coating and coating liquids are provided.

Brief Summary Text (20):
Substrates to which coatings according to the invention may be applied include metals such as stainless steel, nickel, gold, chrome, nickel titanium alloy, platinum and others; plastics such as silicone, polyethylene, other polyolefins, polyesters, and others. Preferred devices include needles, guide wires, catheters, surgical instruments, equipment for endoscopy, wires, stents, angioplasty balloons, wound drains, arteriovenous shunts, gastroenteric tubes, urethral inserts, laparoscopic equipment, pellets, or implants. Particularly preferred embodiments include coated guide wires, particularly mandrel-type wires, catheters, drainage tubes, insulation in pacemaker leads, and smooth thin wires for coronary angioplasty or neurointervention or other procedures requiring a wire thickness of less than about 10-20 mils (250-500 microns).

Brief Summary Text (31):
The tie coat layers of the present invention are extremely durable, even when immersed in water for prolonged periods. As will be shown in examples, coatings on stainless steel can be soaked in water for months without losing adhesion, even when hydrogel layers are applied to the samples. Hydrogel layers typically absorb several times their weight in water and serve as a pathway for water diffusion into the layer (s) between the hydrogel layer and the medical device surface. Such exposure to water, especially for extended periods represents a considerable challenge to the tie coats of the present invention and the fact that they are able to endure such challenges without adhesive failure is a surprising result. The tie coat layers of the present invention are so thin, typically less than 5 microns, that the adhesiveness is all the more remarkable.

CLAIMS:

16. A device according to claim 1 selected from the group consisting of needles, guide wires, catheters, surgical instruments, equipment for endoscopy, wires, stents, angioplasty balloons, wound drains, arteriovenuous shunts, gastroenteric tubes, urethral inserts, laproscopic equipment, pellets, and implants.

DOCUMENT-IDENTIFIER: US 6176849 B1
TITLE: Hydrophilic lubricity coating for medical devices comprising a hydrophobic top coat

Brief Summary Text (4):
Water soluble, biocompatible compounds that impart lubricity to the surface of otherwise non-lubricious materials are desirable for use on medical devices which are inserted or implanted into the body. Such medical devices may include catheters that are utilized to deliver a stent, stent-graft, graft or vena cava filter, balloon catheters, other expandable medical devices and so forth. The industry has turned to hydrophilic lubricious coatings in order to overcome problems with commonly used hydrophobic coatings such as silicone, glycerine or olive oil.

Detailed Description Text (2):
FIG. 2 is a schematic representation of an inflated dilatation balloon catheter of the present invention, illustrated generally at 10. The inflated balloon 14 is mounted at the distal end of an elongated flexible shaft 12. Except as noted herein, catheter 10 is conventional in its construction, providing a lumen communicating with the interior of the balloon 14, for inflation and deflation of the balloon, and other optional features conventional in the dilatation catheter art. The balloon 10, has an inflated configuration, illustrated in FIG. 2 and is made up of three main portions: the body 24, the cones 26 and the waist portions 28. FIG. 1 illustrates the lubricious hydrogel coating 13 and the hydrophobic top coating 15 on the body 24, the cones 26 and the waist 28. FIG. 2 illustrates a coating which is of a uniform thickness on all parts of the balloon. A coating gradient could also be established whereby the coating weight on the body 24, is less than the coat weight on the cones and the coating is thickest on the cone portion closest to the waist and on the waist itself.

Detailed Description Text (4):
FIG. 3 is a schematic representation of an elongated medical device which may be a guide wire, catheter, cannula, fiber optic device and the like. Device 40 extends between proximal end 16 and distal end 18 and includes an elongate body 41. A control mechanism 17 may optionally be provided at or near the proximal end of device 40 to facilitate manipulation of the device and/or activation of functional structure provided on the device, such as drug delivery or balloon inflation lumen. Device 40 may also optionally be provided with a functional structure 19, such as an inflatable balloon, deployable stent, drug delivery mechanism, or the like, typically at or near the distal end 18.

Detailed Description Text (28):
These coatings may be utilized on any insertable or implantable medical instruments or devices including guide wires, catheters, dilatation balloons, stents, stent grafts, grafts, vena cava filter, inflation lumens and so forth.

DOCUMENT-IDENTIFIER: US 6086773 A
TITLE: Method and apparatus for etching-manufacture of cylindrical elements

Abstract Text (1):
A process is described for the manufacture of flexible tubular elements, particularly stents for the medical field, the process comprising the steps of:

Brief Summary Text (3):
The present invention relates to an etched tubular device, particularly cylindrical, biocompatible medical devices for insertion into a body during medical procedures and to a method for manufacturing these devices. More particularly, the invention relates to flexible tubular devices for use as stents, catheters (including, for example, guide catheters and balloon catheters, guidewires, catheter sheaths, microcircuitry containing catheters, catheter introducers and drug infusion catheters/guidewires) and methods for making these devices.

Brief Summary Text (12):
Stents are small, expandable tubes, usually used for insertion into a blocked vessel (vein or artery or duct) or other bodily part. Their physical characteristics must often be the same as those for catheters, except for the fact that they also must be expandable. This expansiveness is effected, not by elastic expansion under pressure, as is the case with balloons or parachutes in surgical procedures, but by more spring-like, metal memory characteristics in the material. Stents are often formed of a metal tube which is compressed (without exceeding the elastic flexibility or stress of the metal), inserted, and then released to allow the stent to expand to its original size and shape.

Brief Summary Text (26):
Stents

Brief Summary Text (27):
Stents are devices that are placed into and/or implanted in the body, and in particular in body structures including vessels, tracts or ducts. For example, stents are commonly used in blood vessels, the urinary tract and in the bile duct, to treat these body structures when they have weakened. With blood vessels, stents are typically implanted therein to treat narrowings or occlusions caused by disease, to reinforce the vessel from collapse or to prevent the vessel from abnormally dilating, as with an aneurysm or the like.

Brief Summary Text (28):
Stents are typically produced at a first smaller diameter for deployment and then expanded to a larger diameter, upon placement into the body vessel, tract, duct or the like. Deployment of stents it typically achieved by mounting the stents on balloon catheters and then once at the requisite position in the body vessel, tract, or duct, expanding the stent to the larger diameter, for permanent placement therein. U.S. Pat. No. 4,856,516 to Hillstead discloses a typical stent and describes a method for its deployment and placement with a balloon catheter.

Brief Summary Text (29):
U.S. Pat. Nos. 5,649,952 and 5,603,721 describes an expandable stent, a method for implanting a stent in a patient and a method for making that type of stent. The stent comprises a cylindrical frame which has patterns of materials removed from the cylindrical mass formed of interconnected elements designed to expand evenly under radial stress. In a preferred structure, a serpentine pattern is formed aligned on a common longitudinal stent axis to form elements that expand evenly under radial stress and maximize the overall radial expansion ratio. Although no methods are claimed in the patent for manufacturing the elements, various methods of manufacture are described such as coating a thin walled tubular element with a material which is

resistant to chemical etchant, removing patterns of the resist material to expose portions of the underlying tubular element, and subsequently etching to remove a pattern of the tubular material which will leave the designed pattern in the tubular element so that it has a pattern which provides the desired expandability. It is stated that it is preferred to apply the etchant resistant coating by electrophoretic deposition and to remove the etchant-resistant material by means of a machine-controlled laser.

Brief Summary Text (31):
WO 97/42910 relates to a novel apertured flexible tubular member with an encasing for insertion into vessels of the body as part of a medical device. For example, the invention can be used as catheters, including guide catheters and balloon catheters, guidewires, catheter sheaths for use with catheter introducers, or drug infusion catheter/guidewires. These catheters also relate to novel apertured flexible tubular stents which may be coated, for insertion into vessels, tracts or ducts. One embodiment is coated with a low friction material such as a low friction polymer so as to provide for lubricity. Samples of materials that might be used are polyurethane, hydrogels, polyethylene, polytetrafluoroethylene (PTFE) and, in particular, one such material which might be used is TEFLON.RTM..

Brief Summary Text (32):
In some embodiments, such as catheters or sheaths, the inside of the flexible tubular member is also preferably coated with a low friction material such as hydrogel and/or with an anticoagulant such as heparin. Another embodiment uses slots of a predetermined configuration cut into a single, hollow, thin-walled metal tube at predetermined spacings, depth and pattern so as to provide the tube with a desired flexibility. The tube is then encased in a suitable low-friction material as noted above or some other suitable coating material. The method of forming the tubular member includes:

Brief Summary Text (45):
The present invention describes a method for providing a flexible cylindrical element, such as a medical stent, comprising the steps of providing a cylindrical body (e.g., a hollow cylindrical body), coating the cylindrical body with a photosensitive resist material (either positive or negative acting), exposing the photosensitive resist material to focused or coherent radiation to which the photoresist composition is sensitive, developing the exposed photosensitive resist material to a fluid developing environment which will selectively remove areas of the photoresist which are more soluble in the fluid developing environment, and then chemically etching exposed surfaces of the cylindrical element which has been exposed by the development of the photoresist coating. The residual photoresist material may be stripped, the patterned cylindrical element cleaned, inspected, packaged and sent to the end user.

Drawing Description Text (2):
FIG. 1 shows a side view of a typical stent within a catheter within a vein.

Drawing Description Text (4):
FIGS. 3(a) and (b) shows front and back views of a flat for supporting multiple cylindrical elements for etching of stents.

Detailed Description Text (3):
A process according to the invention for the manufacture of hollow tubular metal elements, such as flexible stents, comprises the steps of:

Detailed Description Text (35):
FIG. 1 of the present invention shows a vein 1 having a catheter 2 therein. The catheter 2 has within its lumen 3, a pushwire 11 and a stent 10. The stent 10 has open areas 12 which are defined by a sinusoidal pattern of etched metal 13. The stent 10 is typically pushed out of the opening 6 in the catheter 2 and then allowed or forced to expand against the inner surface 5 of the vein. The dimensions of a stent will be dependent upon the particular use to which it is put and the particular vasculature or body part in which it is used. Intracranial stents would be quite small, both in gross diameter and metal thickness, while catheters for ducts and the like from the liver or gall bladder or pancreas would be relatively large. For example, the gaps within a stent (the space between the metal structural material) may be from 0.5 to 7 mils, depending on the area of use, with typical vascular stents having gaps between 2 to 5 mils and preferably from 2.5 to 4.5 mils. The thickness of the structural metal may be from 3 to 10 mils. The practice of the

present invention provides a unique capability of accurately providing relatively thin metal stents, e.g., those having metal thicknesses of less than 6 mils, preferably less than 5 mils, and even from 2 to 4.5 mils, with high resolution and clean edges. This is extremely difficult to effect, and only with the practice of the present invention is this capability known to be provided. One of the difficulties with the prior art techniques is the fact that the chemical etch tends to leave rough surfaces. The thin metal walls of the stent do not allow any significant mechanical smoothing after the etch because of the fragile nature of the porous and open nature of the stent. The width of the metal in the stent (which describes the gaps or openings in the stent) are again determined by the design and use of the final stent product. These gaps are limited only by the resolution of the imaging technology, the strength of the metal, and the quality of the chemical etch. The present invention optimizes these qualities so that metal widths of less than 2 mils, even less than 1.5 mils, can be produced. It is preferred that the metal width be between 0.5 to 10 mils,

Detailed Description Text (51):
Again, as noted earlier, one of the advantages of the system is to keep the metal element rotating continually so that a nearly continuous process can be performed on each metal element. The metal element may comprise a long section of metal tubing so that a number of stents may be imaged on the single tube and then the tube cut into appropriate segments, each of which is a stent.

Detailed Description Text (53):
This is a step often done in the positive printing plate art, which is a type of resist or differential surface tension imaging system. It is not known to be used in the photolithographic imaging and etching of stents as practiced in the present invention. The bum-in may be affected by the application of heat, the application of UV, visible, or infrared radiation to which the photosensitive media was sensitive, or to infrared radiation as an alternative source of heat. The energy additions for the burn-in may also be combined. The burning step may be performed after the development step (which is listed herein as step 11).

Detailed Description Text (55):
It is preferred that this contact be an active contact, that is a contact with some kinetic activity as by stirring a solution in which the element has been placed, swishing the element through a solution, spraying the solution against the surface, or the like); an optional scumming (scum removal) treatment with optical powder, pumice scrub, or the like to mildly remove or abrade away scumming to make the surface to be chemically etched more uniform in properties can be performed about here in the sequence of steps. It is to be noted that the removal of residual resist material within the finely developed image areas by the use of particulate materials in a slurry (e.g., particles having an average particle diameter of less than 25 microns or less than 20 microns, preferably an average particle diameter of less than 10 microns with a particle size variation of less than 25 number percent of the particles having a deviation above the average particle size of more than 30% (and preferably no more than 25%). It is also preferred to use a very fine slurry of particulates with average particles sizes less than 5, preferably less than 3 and even less than 2 microns in average particle size diameter. The particulate slurries are applied to the developed resist image with mild agitation or pressure and then followed with a rinsing step (e.g., step 12, following). This has been found to provide a sharper image, which is not believed to have been disclosed within the photoresist imaging art for non-flat (e.g., three dimensional or especially cylindrical) resist imaging.

Detailed Description Text (60):
The metal tube may be rotated in the etch solution with mild stirring or agitation of the solution to get a uniform etch on all sides of the element (e.g., by placing the metal element on a preferably non-etchable support element or rod which is rotated); again, a spray of the chemical etch, rather than immersion, appears to be uniquely beneficial to the formation of the cylindrical patterned elements of the present invention. Rather strong etch solution may have to be used, depending most particularly upon the nature of the metal, as with nickel containing metals requiring stronger and more frequently replenished etchant solutions. For example, a typical etch will contain ferric chloride solution. Additional materials may include hydrofluoric acid, nitric acid, ammonium difluoride, hydrochloric acid (as a trace from the ferric chloride or as an additive material). It has been found to be desirable to operate with a Baume of 47.degree..+-.8 degrees. At the higher Baume levels, especially with ferric chloride, it is necessary to elevate the temperature

of the etch to between 110 and 150.degree. F., preferably between 115 and 135.degree. F. This elevated temperature in combination with Baume levels above 47.5.degree., usually above 47.5 and below 560 Baume and especially between 48 and 530 Baume, is itself novel in three dimensional etching;

Detailed Description Text (62):
The high specific gravity of the etchant solution which is measured on the Baume' scale is surprising in its ability to perform a higher quality, more smooth surface etch than traditional low Baume' etching solutions. Even though the concentration of active agents is higher in the higher Baume' solutions tends to be higher than in the traditional solutions with a Baume' of less than 47.5 (e.g., 47 and lower), the etch is slower (a lower rate or material dissolution or etching), but the quality of the etch (as visually and statistically determined in the roughness of the surface left after etching) is much higher. This is particularly beneficial, if not critical in the manufacture of small medical devices such as catheters and stents. Because these devices must often be small and have thin walls, reduced quality in the etch itself can cause increased waste of materials (which are quite expensive), require attempts at salvaging rough items (which is expensive and difficult, again due to the small and thin nature of the material), and can lead to defects in the device which are not readily found in ordinary inspection (e.g., structural defects in the orientation, structure or crystallinity of the metal materials). The fact that the use of higher Baume' etchant solutions, irrespective of the chemical nature of the etchant solution, can provide this effect, is a significant advance in the manufacture of small metallic articles. This is particularly true where the surface of the article being etched is three dimensional, as opposed to etching on a flat surface. Even though the higher Baume' (specific gravity of greater

Detailed Description Text (68):
The process and materials of the present invention also encompasses techniques for the photolithographic and chemical etching of circuitry onto or into medical inserts such as catheters or stents. The process for this embodiment of the invention would encompass the formation of a partial or complete metal (conductive) coating on the surface of a catheter or stent. It would be preferred if the catheter or stent had a sacrificial layer (preferably non-conductive) under the metal layer. The catheter or stent material should be resistant to an etch useful on the metal coating. The tubular element (the catheter or stent) with the metal coating on it, is coated, imaged and resist developed according to the process described above. That imaging, however, would be in the form of providing negative images (exposed areas for development) of desired electrical patterns (e.g., resistive heating elements, conducting leads, etc.), circuitry, Magnetic Resonance Imaging coils, or the like. After development of the resist layer, the exposed metal can then be etched to provide the positive structure of the desired conductive (metallic) pattern on the catheter or stent. All of the steps and features of the present invention can be used as desired in the practice of such electronic or circuitry preparation on catheters and stents.

Detailed Description Text (70):
I. In the selection of raw materials for stents, the metal tubing is preferably a high quality, uniform composition and uniform thickness metal tube. An example of the preferred metals are Nitinol or 316LSS fully annealed stainless steel. The preferred range of dimensions for tubing used in the present invention comprises:

CLAIMS:

1. A process for the manufacture of flexible stents comprising the steps of: